PATENT
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IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant:	Ib MENDEL-HARTVIG et al.	Conf.:	
Appl. No.:	New	Group:	Unassigned
Filed:	October 10, 2001	Examiner:	Unassigned
For:	ASSAY METHOD AND KIT THEREFOR		

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

October 10, 2001

Sir:

The following preliminary amendments and remarks are respectfully submitted in connection with the above-identified application.

IN THE CLAIMS:

Please amend the claims as follows:

1. (Amended) A method of determining an analyte in a sample comprising the steps of:

a) contacting the sample with a specified amount of a receptor which binds specifically to the analyte to form an analyte/receptor complex, said specified amount of receptor being in excess of that required to bind all analyte in the sample,

b) isolating on a solid phase a specified fraction of the amount of receptor contacted with the analyte, including analyte/receptor complex and unreacted receptor,

c) detecting the amount of analyte/receptor complex in said isolated specified fraction, and

d) from the detected amount of analyte/receptor complex, determining the concentration of analyte in the sample.

4. (Amended) The method according to claim 1 or 2, wherein isolating said specified fraction of the amount of receptor contacted with the sample on the solid phase comprises providing a solid phase having binding sites for the receptor, and after contacting the sample, or an aliquot thereof, with a liquid phase containing the receptor, binding said specified fraction of receptor to the solid phase.

7. (Amended) The method according to claim 1 or 2, wherein isolating said specified fraction of the amount of receptor on the solid phase comprises contacting the sample with a specified amount of receptor, a specified fraction of which amount is immobilized to said solid phase and the remaining amount of receptor being in a liquid phase.

8. (Amended) The method according to claim 1, wherein in step c) the analyte/receptor complex is detected by a labeled detection reagent which binds specifically to the analyte.

10. The method according to claim 1, wherein in step c) the analyte/receptor complex is detected by a labelled detection reagent which binds specifically to the analyte.

11. (Amended) The method according to claim 1, wherein the ratio between said isolated fraction of the amount of active analyte-binding receptor and the total amount of active analyte-binding receptor contacted with the sample is in the range of from about 1:2 to about 1:1000.

12. (Amended) The method according to claim 1, wherein said solid phase binding sites for the receptor are immobilized in a reaction zone of flow matrix.

13. (Amended) The method according to claim 1, wherein the receptor is an antibody or immunoreactive fragment thereof.